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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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| 09/828,794 | 04/10/2001 | Peter J. Wilk | 7883.011-01 | 9962 |

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EXAMINER

BIANCO, PATRICIA

ART UNIT

PAPER NUMBER

3762

DATE MAILED: 05/09/2003

7

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

| | | | |
|-----------------|-------------------|--------------|-------------|
| Application No. | 09/828,794 | Applicant(s) | WILK ET AL. |
| Examiner | Patricia M Bianco | Art Unit | 3762 |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1) Responsive to communication(s) filed on 03 August 2001.

2a) This action is FINAL. 2b) This action is non-final.

3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

4) Claim(s) 35-53 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5) Claim(s) _____ is/are allowed.

6) Claim(s) 35-53 is/are rejected.

7) Claim(s) _____ is/are objected to.

8) Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9) The specification is objected to by the Examiner.

10) The drawing(s) filed on 10 April 2001 is/are: a) accepted or b) objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11) The proposed drawing correction filed on _____ is: a) approved b) disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12) The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a) All b) Some * c) None of:

1. Certified copies of the priority documents have been received.

2. Certified copies of the priority documents have been received in Application No. _____.

3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) The translation of the foreign language provisional application has been received.

15) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) Notice of References Cited (PTO-892)

2) Notice of Draftsperson's Patent Drawing Review (PTO-948)

3) Information Disclosure Statement(s) (PTO-1449) Paper No(s) 5.

4) Interview Summary (PTO-413) Paper No(s). _____.

5) Notice of Informal Patent Application (PTO-152)

6) Other: *Detailed Action* .

DETAILED ACTION

Response to Preliminary Amendment

1. A preliminary amendment was filed 4/10/01 canceling claims 2-34 and adding claims 35-53. A second preliminary amendment was filed 8/3/01 canceling claim 1.

As a result, claims 35-53 are pending and have been examined on the merits.

Specification

2. Applicant is reminded of the proper language and format for an abstract of the disclosure.

The abstract should be in narrative form and generally limited to a single paragraph on a separate sheet within the range of 50 to 150 words. It is important that the abstract not exceed 150 words in length since the space provided for the abstract on the computer tape used by the printer is limited. The form and legal phraseology often used in patent claims, such as "means" and "said," should be avoided. The abstract should describe the disclosure sufficiently to assist readers in deciding whether there is a need for consulting the full patent text for details.

The language should be clear and concise and should not repeat information given in the title. It should avoid using phrases which can be implied, such as, "The disclosure concerns," "The disclosure defined by this invention," "The disclosure describes," etc.

The abstract of the disclosure is objected to because it contains legal phraseology (i.e. "disclosed"). Correction is required. See MPEP § 608.01(b).

3. Claims 41 & 51 objected to because of the following informalities: the claims recite that the vessel section is a "zenograft." This appears to be a grammatical error where applicant is presumably referring to a *xenograft*. The claims have been

examined as though the vessel section is a xenograft. Appropriate correction is required.

 4. The use of the trademark **NITINOL™** has been noted in this application. It should be capitalized wherever it appears and be accompanied by the generic terminology.

Although the use of trademarks is permissible in patent applications, the proprietary nature of the marks should be respected and every effort made to prevent their use in any manner which might adversely affect their validity as trademarks.

Claim Rejections - 35 USC § 102

5. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 35-39, 42-49, 52, & 53 are rejected under 35 U.S.C. 102(b) as being anticipated by Wilk (5,429,144). Wilk discloses a conduit or stent having a first and second end for placement in the heart wall for creating a passage between the left ventricle and a coronary artery (see figure 2A). The stent has an inner layer that is a vascular graft including a natural valve that is taken from the individual prior to the bypass method. The vascular graft is inherently a portion of a blood vessel, therefore, by

definition, it is an autograft since it comes from the same individual. The stent and valve are capable of restricting flow during diastole. (Col. 8, lines 39-58).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

6. Claims 41 & 51 are rejected under 35 U.S.C. 103(a) as being unpatentable over Wilk ('144) in view of Porier et al. (4,118,806). Wilk discloses the invention substantially as claimed, see rejection with respect to claims 35 & 44 supra. Wilk, however, fails to disclose specifically that the vessel is a xenograft material.

Porier discloses valved tubular conduits for placement in the vasculature wherein the blood vessel, which may contain a valve, is a xenograft material. It would have been obvious to one having skill in the art, at the time of the invention, to utilize tissue

engineering developments and substitute the blood vessel in Wilk's conduit with an xenograft vessel as taught by Porier if harvesting a vessel from the individual receiving bypass is not possible since it has been held to be within the general skill of a worker in the art to select a known material on the basis of its suitability for the intended use as a matter of obvious design choice. *In re Leshin*, 125 USPQ 416.

7. Claims 40 & 50 are rejected under 35 U.S.C. 103(a) as being unpatentable over Wilk ('144) in view of Davies et al. (6,197,296). Wilk discloses the invention substantially as claimed, see rejection with respect to claims 35 & 44 supra. Wilk, however, fails to disclose specifically that the vessel is an allograft material.

Davies discloses tissue for use in vascular grafts wherein the tissue is constructed from xenograft material. It would have been obvious to one having skill in the art, at the time of the invention, to utilize tissue engineering developments and substitute the blood vessel in Wilk's conduit with an allograft vessel as taught by Davies if harvesting a vessel from the individual receiving bypass is not possible since it has been held to be within the general skill of a worker in the art to select a known material on the basis of its suitability for the intended use as a matter of obvious design choice. *In re Leshin*, 125 USPQ 416.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA

1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

8. Claims 35-38, 42, & 43 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 28, 30, 18, 19, 24, & 25 of U.S. Patent No. **6,254,564**. Although the conflicting claims are not identical, they are not patentably distinct from each other because both the application claims and the patent claim recite a method for allowing blood to flow or shunt from the left ventricle to the coronary artery via a conduit having a natural valve within the lumen, the valve being part of a section of body vessel, wherein during diastole blood is restricted through the valve. Thus, if a patent was to grant on the pending claims of this application applicant would be granted an unlawful extension of protection beyond the years of the '564 patent.

9. Claims 44-54 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-7, 11, 12, & 13 of U.S. Patent No. **6,254,564**. Although the conflicting claims are not identical, they are not patentably distinct from each other because both the application claims and the patent claim recite a bypass system or conduit for allowing blood to flow or shunt from the left ventricle to the coronary artery via a conduit having a natural valve within the lumen, the

valve being part of a section of body tissue, namely a blood vessel, and wherein during diastole blood is restricted through the valve. Thus, if a patent was to grant on the pending claims of this application applicant would be granted an unlawful extension of protection beyond the years of the '564 patent.

Conclusion

10. Any inquiry concerning the rejections contained within this communication or earlier communications should be directed to examiner Tricia Bianco whose telephone number is (703) 305-1482. The examiner can normally be reached on Monday through Fridays, alternating Fridays off, from 9:00 AM until 6:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Angela Sykes can be reached on (703) 308-5181. The official fax numbers for the organization where this application or proceeding is assigned is (703) 872-9302 for regular communications and for After Final communications (703) 872-9303.

Tricia Bianco
Patent Examiner
Art Unit 3762

pmb *T. Bianco*
May 5th, 2003